Substitu	te for form 1449A&B/I	РТО		Complete if Known			
				Application Number	10/815,340		
INF	ORMATION	DISCLOS	SURE	Filing Date	March 30, 2004		
STA	STATEMENT BY APPLICANT			First Named Inventor	Berzofsky, Jay A.	i	
				Art Unit	1645		
	(Use as many she	ets as necessary)		Exeminer Name	Nicole Kinsey		
Sheet	1	of	2	Attorney Docket Number	015280-368240US		

Examiner Initials *	Cite No. ¹	include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the Item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), votume-issue number(s), publisher, city and/or country where published.	1,
/NK/	AA	Ahmed and Gray, "Immunological memory and protective immunity: understanding their relation," <i>Science</i> 272:54-60 (1996).	
	АВ	Bender et al., "Oral immunization with a replication-deficient recombinant vaccinia virus protects mice against influenza," J. Virol. 70:6418-6424 (1996).	
	AC	Bennink et al., "Influenzal pneumonia: early appearance of cross-reactive T cells in lungs of mice primed with heterologous type A viruses," <i>Immunol.</i> 35:503-509 (1978).	
	AD	Chen et al., "Predominant T-cell receptor $V\beta$ usage of intraepithelial lymphocytes during the immune response to enteric reovirus infection," J. Virol. 71:3431-3436 (1997).	
	AE	Ehl et al., "A functional and kinetic comparison of antiviral effector and memory cytotoxic T lymphocyte populations in vivo and in vitro," .Eur. J. Immunol. 27:3404-3413 (1997).	Г
	AF	Epstein et al., "Mechanism of protective immunity against influenza virus infection in mice without antibodies," J. Immunol. 160:322-327 (1998).	Г
	AG	Gallichan and Rosenthal, "Long-lived cytotoxic T lymphocyte memory in mucosal tissues after mucosal but not systemic immunization," <i>J. Exp. Med.</i> 184:1879-1890 (1996).	
	АН	Gurgo et al., "Envelope sequences of two new United States HIV-1 isolates," Virology 164:531-536 (1988).	
\bigvee	AI	Kulkarni et al., "Cytotoxic T cells specific for a single peptide on the M2 protein of respiratory syncytial virus are the sole mediators of resistance induced by immunization with M2 encoded by a recombinant vaccinia virus," J. Virol. 69:1261-1264 (1995).	
/NK/	AJ	Kundig et al., "On the role of antigen in maintaining cytotoxic T-cell memory," Proc. Natl. Acad. Sci. USA 93:9716-9723 (1996).	

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	Examiner Signature	/Nicole Kinsey/	Date Considered	12/10/2007	ĺ

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1 Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached.

Substitu	te for form 1449A&B/PT0)			Complete if Known
				Application Number	10/815,340
INFO	DRMATION D	DISCLOS	URE	Filing Date	March 30, 2004
STA	STATEMENT BY APPLICANT			First Named Inventor	Berzofsky, Jay A.
				Art Unit	1645
	(Use as many sheets	as necessary)		Examiner Name	Nicole Kinsey
Sheet	2	of	2	Attorney Docket Number	015280-368240US

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Τ³
/NK/	AK	Lohman et al., "Antiviral cytotoxic T lymphocytes in vaginal mucosa of simian immunodeficiency virus-infected rhesus macaques," J. Immunol. 155:5855-5860 (1995).	
	AL.	Miller et al., "Rhesus macaques previously infected with simian/human immunodeficiency virus are protected from vaginal challenge with pathogenic SIVmac239," J. Virol. 71:1911-1921 (1997).	
	АМ	Putkonen et al., "Protection of human immunodeficiency virus type 2-exposed seronegative macaques from mucosal simian immunodeficiency virus transmission," J. Virol. 71:4981-4984 (1997).	
	AN	Quesada-Rolander et al., "Protection against mucosal SIV _{sm} challenge in macaques infected with a chimeric SIV that expresses HIV type 1 envelope," AIDS Res. Hum. Retroviruses 12:993-999 (1996).	
	ÃO	Ratner et al., "Complete nucleotide sequence of the AIDS virus, HTLV-III," Nature 313:277-284 (1985).	
-	AΡ	Rosenthal and Gallichan, "Challenges for vaccination against sexually-transmitted diseases: induction and long-term maintenance of mucosal immune responses in the female genital tract," <i>Semin. Immunol.</i> 9:303-314 (1997).	
	AQ	Sydora et al.," Intestinal intraepithelial lymphocytes respond to systemic lymphocytic choriomeningitis virus infection," Cell. Imunol. 167:161-169 (1996).	
	AR	Takahashi et al., "A single amino acid interchange yields reciprocal CTL specificities for HTV-1 gp160," Science 246:118-121 (1989).	
\bigvee	AS	Taylor and Askonas., "Influenza nucleoprotein-specific cytotoxic T-cell clones are protective in vivo," Immunol. 58:417-420 (1986).	
/NK/	AT	Wang et al., "Mucosal immunization with a DNA vaccine induces immune responses against HIV-1 at a mucosal site," Vaccine 15:821-825 (1997).	

Examiner		Date	12/10/2007
Signature	/Nicole Kinsey/	Considered	12/10/2007

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			Application Number	10/815,340	
INFO	RMATION	DISCLOS	SURE	Filing Date	March 30, 2004
STATEMENT BY APPLICANT			ANT	First Named Inventor	Berzofsky, Jay A.
				Art Unit	1645
	(Use as many sheets as necessary)			Examiner Name	Nicole Kinsey
Sheet	1	of	5	Attorney Docket Number	015280-368240US

	U.S. PATENT DOCUMENTS								
Examiner Initials*	Cite No.	Document Number Number Kind Code ^{2 (Finner)}	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Unes, Where Relevant Passages or Relevant Figures Appear				
/NK/	AA	4,629,783	12/16/86	Cosand	·				
\Box	AB	4,943,628	07/24/90	Rosen et al.					
V	AC	5,030,449	07/09/91	Berzofsky et al.					
/NK/	AD	5,081,226	01/14/92	Berzofsky et al.					
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FOREIGN PATENT DOCUMENTS									
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	1	Country Code ³	Number ⁴	Gnd Code ⁵ (<i>iI known</i>)	MM-DD-YYYY	Applicant of Cited Document	or Relevant Figures Appear	۲	
/NK/	AE	PCT	WO 87/07616		12/17/1987				
/NK/	AF	PCT	0 273 716		12/23/1987				
/NK/	AG	PCT	WO 94/26785		11/24/1994				

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				Application Number	10/815,340	
INFO	RMATION	DISCLOS	SURE	Filing Date	March 30, 2004	
STAT	STATEMENT BY APPLICANT			First Named Inventor	Berzofsky, Jay A.	•
-				Art Unit	1645	
	(Use as many she	ets as necessary)		Examiner Name	Nicole Kinsey	
Sheet	2	of	5	Attorney Docket Number	015280-368240US	

		NON PATENT LITERATURE DOCUM	ENTS				
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the a magazine, journal, serial, symposium, catalog, etc.), date, pag and/or country where put	e(s), volume-iss	propriate), title of the item (book, sue number(s), publisher, city	T²		
/NK/	ning a Multideterminant Neutralizing Antibody mizations," J. Immunol.						
	Ahlers et al., "Candidate HIV Type 1 Multideterminant Cluster Peptide-P18MN Vaccine Constructs Elicit Type 1 Helper T Cells, Cytotoxic T Cells, and Neutralizing Antibody, a Using the Same Adjuvant Immunization," AIDS Res. Hum. Retroviruses 12:259-272 (1996).						
	Allers et al., "Cytokine-in-Adjuvant Steering of the Immune Response Phenotype to HIV-Vaccine Constructs," J. Immunol. 158:3947-3958 (1997).						
	AK	Ahlers et al., "Enhanced Immunogenicity of HIV-1 Vaccine Construct by Modification of the native Peptide Sequence," Proc. Natl. Acad. Sci. USA 94:10856-10861 (1997).					
	AL	Belyakov et al., "Mucosal Immunization with HIV-1 Systemic Cytotoxic T Lymphocytes and Protective In Recombinant HIV-Vaccinia Challenge," Proc. Nat. A	mmunity in N	Mice Against Intrarectal			
	АМ	Berzofsky et al., "Construction of Peptides Encompa Human Immunodeficiency Virus Envelope to Induce Humans of Multiple MHC Types," J. Clinical Invest	In Vitro T C	Cell Responses in Mice and			
	AN	Berzofsky and Berkower, "Novel Approaches to Pep for HIB Using Defined Epitopes: Advances in 1994 (1995).	tide and Eng -1995," <i>AIDS</i>	ineered Protein Vaccines 3 1995 9(A):S143-S157			
	AO	Bomsel, "Transcytosis of Infectious Human Immuno Human Epithelial Cell Line Barrier," Nature Medicin					
$\sqrt{}$	AP	Butini et al., "Comparative Analysis of HIV-Specific Peripheral Blood," J. Cellular Biochemistry Abstract	CTL Activi	ty in Lymphoid Tissue and 147 (1994).			
/NK/	AQ	Cranage et al., "Macaques Infected with Live Attenu Superinfection via the Rectal Mucosa," Virology 229					
Examiner Signature							

	Examiner Signature	/Nicole Kinsey/	Date Considered	12/10/2007
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INFO	RMATION	DISCLOS	SURE	Filing Date	March 30, 2004	
STA	STATEMENT BY APPLICANT			First Named Inventor	Berzofsky, Jay A.	
				Art Unit	1645	
	(Use as many sheet	ts as necessary)		Examiner Name	Nicole Kinsey	
Sheet	3	of	5	Attorney Docket Number	015280-368240US	

			NON PATENT LITERATURE DOCUMENTS	
Examiner Cite No.1			Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	
/NK/ AR		AR	di Tommaso et al., "Induction of Antigen-Specific Antibodies in Vaginal Secretions by Using a Nontoxic Mutant of Heat-Labile Enterotoxin as a Mucosal Adjuvant," Infection and Immunity 64:974-979 (1996).	
		AS	Douce et al., "Intranasal Immunogenicity and Adjuvanticity of site-directed mutant derivatives of cholera toxin," Infection and Immunity 65:2821-2828 (1997).	
	***************************************	ΑT	Gallichan et al., "Long-Lived Cytotoxic T Lymphocyte Memory in Mucosal Tissues After Mucosal but not Systemic Immunization," J. Exp. Med. 184:1879-1890 (1996).	
		AU	Graham et al., "Candidate AIDS Vaccines," New England Journal of Medicine 333:1331-1339 (1995).	
	AW AX		Hale et al., "T Cell Multideterminant Regions in the Human Immunodeficiency Virus Envelope: Toward Overcoming the Problem of Major Histocompatibility Complex Restriction," International Immunology 1:409-415 (1989).	
			Haynes, B.F., "Scientific and Social Issues of Human Immunodeficiency Virus Vaccine Development," Science 260:1279-1286 (1993).	
			Klavinskis et al., "Mucosal or Targeted Lymph Node Immunization of Macaques with a Particulate SIVp27 Protein Elicits Virus-Specific CTL in the Genito-Rectal Mucosa and Draining Lymph Nodes," J. Immunol. 157:2521-2527 (1996).	
AY		AY	Kozlowski et al., "Serum Angiotensin-1 Converting Enzyme Activity Processes a Human Immunodeficiency Virus 1 Gp160 Peptide for Presentation by Major Histocompatibility Complex Class I Molecules," J. Exp. Med. 175:1417-1422 (1992).	
	/	ΑZ	Langermann, S., "New Approaches to Mucosal Immunization," <i>Seminars in Gastrointestinal Disease</i> 7:12-18 (1996).	
/N	ık/	ВА	Lehner et al., "Protective Mucosal Immunity Elicited by Targeted Iliac Lymph Node Immunization with a Subunit SIV Envelope and Core Vaccine in Macaques," Nature Medicine 2:767-775 (1996).	

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Examiner Signature	/Nicole Kinsey/	Date Considered	12/10/2007

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Substitute	for form 1449A&B/PTO			Complete If Known		
				Application Number	10/815,340	
INFO	RMATION DIS	CLOS	SURE	Filing Date	March 30, 2004	
STAT	EMENT BY A	PPLIC	CANT	First Named Inventor	Berzofsky, Jay A.	
				Art Unit	1645	
. ((Use as many sheets as r	necessary)		Examiner Name	Nicole Kinsey	
Sheet	4	of	5	Attorney Docket Number	015280-368240US	

			NON PATENT LITERATURE DOCUMENTS	
Examiner Cite No.1			Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	
/NK/ BE		BB	Miller et al., "Genital Mucosal Transmission of Simian Immunodeficiency Virus: Animal Model for Heterosexual Transmission of Human Immunodeficiency Virus," J. Virol. 63:4277-4284 (1989).	
		BC	Modrow et al., "Computer- Assisted Analysis of Envelope Protein Sequences of Seven Human Immunodeficiency Virus Isolates: Prediction of Antigenic Epitopes in Conserved and Variable Regions," J. Virol. 61:570-578 (1987).	
		BD	Musey et al., "HIV-1 Induces Cytotoxic T Lymphocytes in the Cervix of Infected Women," J. Exp. Med. 185:293-300 (1997).	
ВЕ		BE	Neutra et al., "Antigen Sampling Across Epithelial Barriers and Induction of Mucosal Immune Responses," Annu. Rev. Immunol. 14:275-300 (1996).	
BF		BF	Parditos et al., "Antibody Responses to Non-Immunogenic Synthetic Peptides Induced by Co-Immunization with Immunogenic Peptides," Immunology 77:262-266 (1992).	
BG		BG	Parditos et al., "Mucosal Immunization with a Measles Virus CTL Epitope Encapsulated in Biodegradable PLG Microparticles," J. Immun. Meth. 195:135-138 (1996).	
••••••		ВН	Parditos et al., "The Adjuvant Effect of a Non-Toxic Mutant of Heat-Labile Enterotoxin of Escherichia Coli for the Induction of Measles Virus-Specific CTL Responses After Intranasal Co-Immunization with a Synthetic Peptide," Immunology 89:483-487 (1996).	
		BI	Porgador et al., "Intranasal Immunization with CTL Epitope Peptides from HIV-1 or Ovalbumin and the Mucosal Adjuvant Cholera Toxin Induces Peptide-Specific CTLs and Protection Against Tumor Development in Vivo," J. Immunol. 158:834-841 (1997).	
	/	ВЈ	Shirai et al., "Broad Recognition of Cytotoxic T Cell Epitopes from the HIV-1 Envelope Protein with Multiple Class I Histocompatibility Molecules," J. Immunol. 148:1657-1667 (1992).	
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Examiner Signature	/Nicole Kinsey/	Date Considered	12/10/2007

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Substitute	for form 1449A&B/PT(D		Complete if Known		
				Application Number	10/815,340	
INFO	RMATION D	DISCLOS	SURE	Filing Date	March 30, 2004	
STATEMENT BY APPLICANT				First Named Inventor	Berzofsky, Jay A.	
				Art Unit	1645	
	(Use as many sheets	as necessary)		Examiner Name	Nicole Kinsey	
Sheet	5	of	5	Attorney Docket Number	015280-368240US	

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		Takahashi et al., "An Immunodominant Epitope of the Human Immunodeficiency Virus Envelope Glycoprotein Gp160 Recognized by Class I Major Histocompatibility Complex Molecule-Restricted Murine Cytotoxic T Lymphocytes," Proc. Natl. Acad. Sci. USA 85:3105-3109 (1988).			
	ВМ	Takahashi et al., "Induction of Broadly Cross-Reactive Cytotoxic T Cells Recognizing an HIV-1 Envelope Determinant," Science 255:333-336 (1992).			
	BN	Takeshita et al., "Molecular Analysis of the Same HIV Peptide Functionally Binding to Both a Class I and a Class II MHC Molecule," J. Immunol. 154:1973-1986 (1995).			
\bigvee	во	Yamamoto et al., "Mutants in the ADP-ribosyltransferase Cleft of Cholera Toxin Lack Diarrheagenicity but retain adjuvanticity," J. Exp. Med. 185:1203-1210 (1997).			
/NK/	BP	Yamamoto et al., "A nontoxic mutant of cholera toxin elicits Th2-type responses for enhanced mucosal immunity," Proc. Natl. Acad. Sci. USA 94:5267-5272 (1997).			
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Examiner Signature	/Nicole Kinsey/	Date Considered	12/10/2007	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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